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EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT PAPER NUMBER
1645

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24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/376,911

Applicant(s)

Michon et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 28, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 8-22, 24-28, 37-40, 59-61, and 63 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 8-22, 24-28, 37-40, 59-61, and 63 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Request for Continued Examination

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 04/28/03 (paper no. 22) has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 04/28/03 (paper no. 23) in response to the final rejection mailed 10/29/02 (paper no. 17). With this Applicants have amended the specification.

Status of Claims

3) Claims 2, 6-7, 29-36, 41-58 and 62 have been canceled via the amendment 04/28/03. Claims 1, 4, 15-21, 25, 59-61 and 63 have been amended via the amendment filed 04/28/03. Since claim 23 has not been presented in the amendment filed 04/28/03, it is assumed to be non-existent.

Claims 1, 3-5, 8-22, 24-28, 37-40, 59-61 and 63 are pending and are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 7(a) of the Office Action mailed 01/28/02 (paper no. 11) is withdrawn in light of Applicants' amendment to the first paragraph of the specification.

7) The objection to the specification made in paragraph 7(c) of the Office Action mailed 01/28/02 (paper no. 11) is withdrawn in light of Applicants' arguments.

Rejection(s) Moot

- 8) The rejection of claim 23 made in paragraph 38 of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot for the reason set forth in paragraph 3 above.
- 9) The rejection of claim 23 made in paragraph 39(h) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot for the reason set forth in paragraph 3 above.
- 10) The rejection of claims 23 made in paragraph 22 of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 36 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C § 103(a) as being unpatentable over Pon RA (*The Study of Polysialic acid Conjugates*. Master's Thesis, University of Ottawa, pp. 1-251, UMI Dissertation Services, 1992) and Blake *et al.* (US 5,439,808), is moot for the reason set forth in paragraph 3 above.

Rejection(s) Withdrawn

- 11) The rejection of claims 18 and 20 made in paragraph 8 of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 33 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendment to the base claims.
- 12) The rejection of claims 4 and 17 made in paragraph 11(d) of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 35 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.
- 13) The rejection of claims 1-5, 8-22, 24-28, 37-40 and 59-63 made in paragraph 38 of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn.
- 14) The rejection of claims 1 and 16 made in paragraph 39(a) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.
- 15) The rejection of claims 4, 15, 59, 61 and 63 made in paragraph 39(b) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

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- 16) The rejection of claims 60 and 62 made in paragraph 39(c) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.
- 17) The rejection of claim 4 made in paragraph 39(c) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.
- 18) The rejection of claims 59 and 61 made in paragraph 39(d) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.
- 19) The rejection of claims 1 and 16 made in paragraphs 39(e) and 39(f) respectively of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn partly in light of Applicants' amendments to the claims.
- 20) The rejection of claim 16 made in paragraph 39(g) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 21) The rejection of claims 2-5, 8-15, 17-22, 24-28, 37-40 and 59-63 made in paragraph 39(h) of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the base claims.

Rejection(s) Maintained

- 22) The rejection of claims 37-40 made in paragraph 10 of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 34 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is maintained for reasons set forth therein.

Applicants point to the section 'Vaccines' on page 12 of the specification and acknowledge that the conjugates of the present invention are used as 'antigens to generate antibodies that are reactive against the organism or cell from which the polysaccharide or oligosaccharide was isolated' [Emphasis in original]. Applicants conclude that one skilled in the art would understand that the vaccines comprising the polysaccharide protein conjugate would be 'immunogenic' to the organism or cell from which the polysaccharide was obtained.

Applicants' arguments have been carefully, considered, but are non-persuasive. As set forth in paragraph 34 of the Office Action mailed 10/29/02 (paper no. 17), the conjugate recited in the claims is required to provide 'protective immunity against at least one member of a genus of an organism from which the polysaccharide or oligosaccharide component of the polysaccharide-protein conjugate or oligosaccharide-protein conjugate was obtained'. The claimed conjugate is not merely required to be 'immunogenic'. The term 'at least' is equivalent to any number that exceeds one. The part of the specification pointed to by Applicants on page 12 does not even mention of (let alone provide enablement) any 'protective immunity' against 'at least one member of a genus of an organism' from which the polysaccharide or oligosaccharide was obtained. No mention of a 'member' or a 'genus' of any organism is made here. Antibody "reactivity" is not equated to 'protective immunity'. Whether or not a 'member' represents a species of a genus, a strain, or an isolate is not described. As Applicants readily acknowledge, page 12 of the specification describes that the polysaccharide or oligosaccharide conjugates of the instant invention would only elicit antibodies to the organism or cell from which the polysaccharide was obtained. For reasons set forth in paragraph 34 of the Office Action mailed 10/29/02 (paper no. 17), the rejection stands.

23) The rejection of claims 3 and 5 made in paragraph 11(d) of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 35 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C. § 112, second paragraph, as being indefinite, is still maintained for reasons set forth therein.

24) The rejection of claims 1 and 8-10 made in paragraph 21 of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 36 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C § 103(a) as being unpatentable over Pon RA (*The Study of Polysialic acid Conjugates*. Master's Thesis, University of Ottawa, pp. 1-251, UMI Dissertation Services, 1992) in view of Blake *et al.* (US 5,439,808), is maintained for reasons set forth therein and herebelow.

25) The rejection of claims 1, 16, 22 and 24 made in paragraph 22 of the Office Action mailed 01/28/02 (paper no. 11) and maintained in paragraph 36 of the Office Action mailed 10/29/02 (paper no. 17) under 35 U.S.C § 103(a) as being unpatentable over Pon RA (*The Study of Polysialic acid Conjugates*. Master's Thesis, University of Ottawa, pp. 1-251, UMI Dissertation Services, 1992) and Blake *et al.* (US 5,439,808), is maintained for reasons set forth therein and herebelow.

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26) The rejection of claims 1-4, 11-14, 16, 17, 19-22, 26-28, 37-39 and 59-63 made in paragraph 40 of the Office Action mailed 08/18/99 (paper no. 17) under 35 U.S.C. § 103(a) as being unpatentable over Pon RA (*The Study of Polysialic acid Conjugates*. Master's Thesis, University of Ottawa, pp. 1-251, UMI Dissertation Services, 1992) and Blake *et al.* (US 5,439,808), is maintained for reasons set forth therein and herebelow.

Applicants contend that the percent of polysaccharide or oligosaccharide that is de-N-acetylated varies from the present invention to what is reported in the Pon reference. Applicants point to parts of the Pon reference and state that the colominic acid therein has only been de-N-acetylated by about 15%, but not by at least 50%. Applicants assert that Pon does not teach or suggest that 15% N-acryloylated colominic acid conjugates can elicit the production of protective antibodies. With regard to Blake *et al.*, Applicants submit that Blakes' disclosure relates to the use of porin as a protein carrier in conjugate vaccines, but does not teach or suggest the conjugate vaccines of the present invention which possesses the beta-propionamido linkage. Applicants state that Blake is silent about the at least 50% of the N-propionated polysaccharide being de-N-acetylated. Applicants conclude that the combination of Pon and Blake references do not teach or suggest the claimed invention and do not provide any motivation to adjust the percentage of acetyl groups that are removed.

Applicants' arguments have been carefully considered, but are non-persuasive. If Pon or Blake *et al.* taught all of the claimed elements, then Pon or Blake *et al.* would have been applied as anticipatory references under 35 U.S.C. § 102 as opposed to 35 U.S.C. § 103. Applicants' reference to Pon's teaching on page 202 is pertinent to the interaction of structurally modified polysaccharides with horse 46 antiserum and has nothing to do with N-propionated polysaccharide or oligosaccharide in a conjugate. Additionally, Pon's Table 5-2 provides the *prima facie* evidence that colominic acid, with more than 15% de-N-acetylation or even with more than 50% de-N-acetylation, retained its antigenicity with H.46 antiserum. Furthermore, Table 5-3 depicts that both N-acryloyl and N-propionyl colominic acids showed strong precipitin bands with H.46 antiserum. With this, one of skill in the art would have been motivated to increase the percent de-N-acetylation and subsequent N-acryloylation to at least 50% by routine experimentation. It should be noted that no evidence is of record in the instant disclosure establishing that the recited percentages of N-acryloylation or de-

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N-acetylation are critical for the invention. It has been held legally obvious and within the routine skill in the art to optimize a result effected variable. In the instant case, the percent N-acryloylation or de-N-acetylation of the polysaccharide or oligosaccharide in the claimed conjugate is clearly a result effected variable, and it would have been obvious to one of ordinary skill in the art at the time of the invention to vary or optimize the percent N-acryloylation or de-N-acetylation of the polysaccharide or oligosaccharide in Pons' conjugate as modified by Blake *et al.* to more than 50% by routine experimentation to produce the instant invention. That Pon's conjugate as modified by Blake elicits colominic acid-specific IgG or IgM antibody, and protective antibodies is implicit from the combined teachings of the prior art. The rejection stands.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

27) Claims 37-40 and those that depend from these claims are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 37, as amended via the amendment filed 04/23/02, includes the limitations: 'at least one member of a genus of an organism from which the polysaccharide or oligosaccharide component of the polysaccharide-protein conjugate or oligosaccharide-protein conjugate was extracted'. However, there appears to be no descriptive support in the specification, as originally filed, for these added limitations. Therefore, the above-identified limitations in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

28) Claims 1, 16 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 16, as amended, includes the limitations: 'the N-propionated polysaccharide or

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N-propionated oligosaccharide directly coupled to the protein elicits protective antibodies reactive against the N-propionated polysaccharide or N-propionated oligosaccharide; wherein the N-propionated polysaccharide or N-propionated oligosaccharide is de-N-acetylated and N-acryloylated; wherein at least 50% of the N-propionated polysaccharide or oligosaccharide is de-N-acetylated...'. Claims 59 and 60 depend from claim 1 and encompass or recite a polysaccharide or the

oligosaccharide that is at least 95% N-acryloylated. Applicants point to page 23, lines 1-6 and page 14, lines 23-27; page 3, line 13; and page 9, line 30 through page 10, line 5 of the specification as providing descriptive support for the added limitations. However, there is no support in these parts of the specification for a polysaccharide- or oligosaccharide-protein as recited, having at least 50% or 95% of the N-propionated polysaccharide or oligosaccharide elicits 'protective' antibodies reactive against the N-propionated polysaccharide or oligosaccharide. Therefore, the above-identified limitations in the claims is considered to be new matter. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

29) Claims 1, 3-5, 8-22, 24-28, 37-40, 59-61 and 63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 24 depends from a currently non-existent claim, i.e., claim 23.

(b) Claims 3, 5, 8-14 and 37 lack antecedent basis for the recitation: "The conjugates according to claim .." [Emphasis added]. Instant claims depend directly or indirectly from claim 1, which is directed to "A conjugate", but not more than one conjugate. To be consistent with the correct claim language used in claims 4, 15, 59, 61 and 63, it is suggested that Applicants replace the recitation with --The conjugate according to claim--.

(c) Claims 3, 5, 11 and 12 have improper antecedent basis in the recitation: "the saccharide ..." [Emphasis added]. Instant claims depend from claim 1 which does not recites any

“saccharide”.

(d) Claims 1 and 16, as amended, include the limitation: “elicits protective antibodies reactive against the N-propionated polysaccharide or N-propionated oligosaccharide”. While it appears that the reactivity of the antibodies elicited by the claimed conjugate is ‘with’ N-propionated polysaccharide or N-propionated oligosaccharide, it is still unclear what are these N-propionated polysaccharide- or N-propionated oligosaccharide-reactive antibodies protective ‘against’. The need for protection ‘against’ an isolated or non-isolated N-propionated polysaccharide or N-propionated oligosaccharide is not understood. It should be noted that the source or origin of the polysaccharide or oligosaccharide is undisclosed in the instant claims and therefore broadly encompass a polysaccharide or oligosaccharide from any source, including nature, environment, a plant, an animal, or self antigens. Even if one assumed that the protectivity is against bacteria or a host cell from which the polysaccharide or oligosaccharide is obtained from, since the polysaccharide or oligosaccharide on the bacterium or a host cell from which these are obtained is present on their surface in native or unmodified form, i.e., non-N-propionated form, it is not clear how N-propionated polysaccharide- or N-propionated oligosaccharide-reactive antibodies can be ‘protective against’ bacteria or host cells that possess the native non-N-propionated polysaccharide. If one used an N-propionated plant polysaccharide or oligosaccharide in the claimed conjugate, it is not clear what would the resultant antibodies be protective against. Clarification/correction is requested.

(e) Claims 26 and 27 are indefinite and/or improperly broadening in scope in the recitation ‘polysaccharide-specific’ or ‘oligosaccharide-specific’ immune response or immunoglobulin. Claims 26 and 27 depend from claims 1 and 16 respectively, which recite a polysaccharide or oligosaccharide of much narrower scope, i.e., N-propionated polysaccharide or N-propionated oligosaccharide.

(f) Claim 39 is incorrect in the recitation: ‘bacteria is’ [Emphasis added].

(g) Claim 61 does not further limit claim 1.

(h) Claims 3-5, 8-15, 17-22, 24-28, 37-40, 59-61 and 63, which depend directly or indirectly from claim 1 or 16, are also rejected as being indefinite, because of the vagueness or indefiniteness identified above in the base claim.

Objection(s)

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- 30) Claims 3-5, 14, 17, 38 and 39 are objected to for the following reason(s):
- (a) Claim 14 is confusing and/or incorrect in the recitation: 'an -free amino group'.
 - (b) Claims 3-5, 17, 38 and 39 are objected to for including the non-elected subject matter.


Remarks

- 31) Claims 1, 3-5, 8-22, 24-28, 37-40, 59-61 and 63 stand rejected.
- 32) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 33) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July, 2003


S. DEVI, PH.D.
PRIMARY EXAMINER